



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 18 2007

Pulsion Medical Systems AG  
c/o Dr. Jamie Sulley  
President  
Triangulum Consulting Services, Inc.  
7220 Sparhawks Road  
Wake Forest, NC 27587

Re: K072735  
Trade Name: Pulsion PiCCO-2, Model 8500  
Regulation Number: 21 CFR 870.1435  
Regulation Name: Single Function Pre-Programmed Diagnostic Computer  
Regulatory Class: Class II (two)  
Product Code: DXG  
Dated: September 25, 2007  
Received: September 27, 2007

Dear Dr. Sulley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "B. Zuckerman for".

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

#### 4.0 INDICATIONS FOR USE STATEMENT

### Indications for Use

510(k) Number (if known): K072735

Device Name: PiCCO-2

Indications for Use:

The PULSION PiCCO-2 is intended for determination and monitoring of cardiopulmonary and circulatory variables. Cardiac output is determined both continuously through pulse contour analysis and intermittently through thermodilution technique. In addition, the PiCCO-2 measures heart rate, systolic, and diastolic and derives mean arterial pressure. Analysis of thermodilution curve in terms of mean transit time and downslope time is used for determination of intravascular and extravascular fluid volumes. If a patient's weight and height are entered, the PiCCO-2 presents the derived parameters indexed to body surface area.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

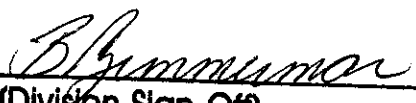
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K072735

Page 1 of 1

(Posted November 13, 2003)